UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,134	02/11/2005	Scott Koenig	11183-003-999	1503

20583 7590 11/30/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
CROWDER, CHUN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/524,134	KOENIG ET AL.	
	Examiner	Art Unit	
	Chun Crowder	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-107* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

2. For examination purposes the following is noted:

Independent claim 1 recites "an isolated antibody or fragment thereof that specifically binds native FcγRIIB". Dependent claim 2 recites that the binding agonizes the activity of FcγRIIB, whereas dependent claim 9 recites that the binding antagonizes the activity of FcγRIIB. These functional limitations are mutually exclusive in that they reach the opposing endpoints, and in that they employed distinct antibodies to accomplish these mutually exclusive endpoints. In addition, dependent claims 24-26 read on bispecific antibodies.

Consequently, the claims have been limited to either agonistic, antagonistic or bispecific antibodies, irrespective of the format of the claims.

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-8, 16-21, 23, 27-32, 34, 36-43, 81-90, 104-107, drawn to an isolated antibody or a fragment thereof that specifically binds native FcγRIIB with greater affinity wherein the binding agonizes at least one activity of FcγRIIB.

II. Claims 1, 9-21, 23, 27-32, 34, 36-43, 81-90, 104-107, drawn to an isolated antibody or a fragment thereof that specifically binds native FcγRIIB with greater affinity wherein the binding antagonizes at least one activity of FcγRIIB.

Applicant is invited to indicate which group claims 36-43 belong to.

III. Claims 22, and 24-26, drawn to a bispecific antibody that binds FcγRIIB and a tumor antigen.

For examination purposes, claims 24-26 read on bispecific antibodies.

IV. Claims 33, 35, 91, and 92, drawn to a method of producing a monoclonal anti- FcγRIIB antibody by immunizing FcγRIIA transgenic mice.

V. Claims 44-50, drawn to an isolated nucleic acid encoding agonizing anti FcγRIIB antibody, a vector, a host cell and a method of producing the antibody.

VI. Claims 44-50, drawn to an isolated nucleic acid encoding antagonizing anti FcγRIIB antibody, a vector, a host cell and a method of producing the antibody.

VII. Claims 51-59, 77, and 93-103, drawn to a method of treating cancer characterized by a cancer antigen comprising administering antibody that specifically binds FcγRIIB and a second antibody.

VIII. Claims 60-64, drawn to a pharmaceutical composition comprising an anti-FcγRIIB antibody, an antibody specific for cancer antigen and a carrier.

IX. Claims 65-72, 75, and 76, drawn to a method of treating an autoimmune disorder by administering an antibody specific for FcγRIIB.

X. Claim 73-76, drawn to a method of treating or preventing an IgE-mediated allergic disorder by administering an antibody specific for FcγRIIB.

XI. Claims 78 and 79, drawn a method of diagnosis of an autoimmune disease.

XII. Claim 80, drawn to a method of enhancing an immune response to a vaccine composition by administering an antibody specific for FcγRIIB and a vaccine composition.

XIII. Claims 96, 97, 100-103, drawn to a method of treating a disease by administering an antibody specific for FcγRIIB and a non-cell killing antibody.

4. The inventions listed as Group I-XIII do not related to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

5. The inventions of Groups I-II were found to have no special technical feature that defined a contribution over the prior art Presta (US Patent Application NO: 2004/0191244) (see entire document).

Presta teaches methods of making antibody with altered effector functions. Specifically, Presta teaches that by replacing amino acids in the Fc receptor binding sites of antibody Fc region may increase binding affinity to Fc receptor including FcγRIIB (e.g. see pages 2-3 and Figure 19A).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art, they do not have a single inventive concept and so lack unity of invention.

Species Election

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are no so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

7. If any one of the Groups I-XIII is elected, applicant is required to elect:

(a) one specific antibody produced by a specific hybridoma (e.g.clone 3H7), **AND**

(b) which, if any, of the functional limitations recited, e.g., in claims 2-8 are encompassed by the elected antibody species.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8. In addition, if any one of Groups I and II is elected, applicant is required to elect one specific antibody:

(a) without conjugation, **OR**

(b) conjugated to one specific therapeutic agent.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. If any one of Groups III, VII, and VII is elected, applicant is further required to elect an ultimate species wherein the second heavy-light chain pair binds to:

(a) one **specific** tumor antigen, **AND**

(b) one **specific** cancer as it reads on the elected tumor antigen species.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. If Group IX is elected, applicant is further required to elect method of treating
(a) one **specific** autoimmune disorder (e.g. rheumatoid arthritis), **AND**
(b) administering **specific** immunomodulatory agents.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

11. If Group X is elected, applicant is further required to elect a method of treating one **specific** disease (e.g. asthma).

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. If Group XI is elected, applicant is further required to elect a method of diagnosis using one **specific** detectable marker.

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

13. If Group XIII is elected, applicant is further required to elect a method of treating by administering one **specific** second non-cancer-antigen-binding antibody (e.g. anti-Fas antibody).

These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that the response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Crowder whose telephone number is (571) 272-8142. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chun Crowder, Ph.D.
Patent Examiner
November 15, 2005

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER